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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,222	04/09/2004	Heidi Schmitt	33449801 IUS	1315
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PERKINS COIE LLP/CARGILL, INC. P.O. BOX 1247 SEATTLE, WA 98111-1247				
			EXAMINER	
			FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,222

Applicant(s)

SCHMITT ET AL.

Examiner

Allison M. Ford

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-28 is/are allowed.
- 6) ☒ Claim(s) 29,30,32,33,35 and 36 is/are rejected.
- 7) ☒ Claim(s) 31 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 17 July 2006 to claims 1, 17, 18 and 29 have been entered. Claims 1-36 remain pending in the current application, all claims have been considered on the merits.

Claim Objections

Claims 31 and 34 are objected to as being dependent upon a rejected base claim (claim 29), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 30 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Haas et al (J American Oil Chem. Soc., 1995).

Applicant's claim 29 is directed to a method of producing a product comprising phospholipids, monoglycerides and diglycerides by enzymatic hydrolysis, the method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aqueous medium or an organic solvent medium comprising an aprotic organic solvent and sufficient water to promote hydrolysis, with a lipase which selectively hydrolyzes said triglycerides, and obtaining the hydrolyzed lecithin product. Claim 30 requires the solvent medium to be an organic solvent medium. Claim 32 requires the phospholipids to make up at least 50% of the lecithin mixture.

Haas et al study the hydrolytic activity of three different lipases in an organic solvent on mixtures of phospholipids and triglycerides. Haas et al used Lipase AY-30, Lipozyme IM20 and Novozyme 435 as the lipases (See Haas et al, Table 2). Haas et al used three different substrates: (i) a mixture of pure phosphatidylcholine (22 mM) and soy triglycerides (22mM) (50:50 mixture, thus phospholipids comprise 50% of lecithin); (ii) a mixture of semi-pure phosphatidylcholine (25mM) and soy triglycerides (22mM) (approximately 53:47 mixture, thus phospholipids comprise over 50% of lecithin material); and soybean soapstock (0.5g/reaction) (See Haas et al, Pg. 520, col.2). All substrates comprised a mixture of phospholipids and triglycerides, which applicant defines as a lecithin material. Each of the substrates were dissolved in hexane, 60uL of water was added to the mixtures of substrates (i) and (ii) to provide sufficient water to promote enzyme activity (See Haas et al, Pg. 520, col. 2 & Pg. 521, col. 2); then the substrate mixtures were contacted with one of the three lipases; the lecithin products were recovered via HPLC; and the degree of hydrolysis was measured (See Haas et al, Pg. 520, col. 2- Pg. 521, col. 1).

Haas et al report at least the AY-30 lipase selectively hydrolyzed the triglycerides of semi-pure PC/triglyceride substrate (ii); specifically Haas et al report the AY-30 lipase completely hydrolyzed the soy triglycerides within 20 hours, but failed to hydrolyze the phospholipid component (See Haas et al, Pg. 521, col. 2- Pg. 522, col. 1). Therefore, Haas et al teach a method of producing a hydrolyzed product, said method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aprotic organic solvent medium comprising sufficient water to promote hydrolysis, with a lipase which selectively hydrolyzes the triglycerides, in the absence of any phospholipase (Claims 29, 30 and 32). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 30, 32, 33, 35 and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Haas et al (J American Oil Chem. Soc., 1995).

Haas et al study the hydrolytic activity of three different lipases in an organic solvent on mixtures of phospholipids and triglycerides. Haas et al used Lipase AY-30, Lipozyme IM20 and Novozyme 435 as the lipases (See Haas et al, Table 2). Haas et al used three different substrates: (i) a mixture of pure phosphatidylcholine (22 mM) and soy triglycerides (22mM) (50:50 mixture, thus phospholipids comprise 50% of lecithin); (ii) a mixture of semi-pure phosphatidylcholine (25mM) and soy triglycerides (22mM) (approximately 53:47 mixture, thus phospholipids comprise over 50% of lecithin material); and soybean soapstock (0.5g/reaction) (See Haas et al, Pg. 520, col.2). All substrates comprised a mixture of phospholipids and triglycerides, which applicant defines as a lecithin material. Each of the substrates were dissolved in hexane, 60uL of water was added to the mixtures of substrates (i) and (ii) to provide sufficient water to promote enzyme activity (See Haas et al, Pg. 520, col. 2 & Pg. 521, col. 2); then the substrate mixtures were contacted with one of the three lipases; the lecithin products were recovered via HPLC; and the degree of hydrolysis was measured (See Haas et al, Pg. 520, col. 2- Pg. 521, col. 1).

Haas et al report at least the AY-30 lipase selectively hydrolyzed the triglycerides of semi-pure PC/triglyceride substrate (ii); specifically Haas et al report the AY-30 lipase completely hydrolyzed the soy triglycerides within 20 hours, but failed to hydrolyze the phospholipid component (See Haas et al, Pg. 521, col. 2- Pg. 522, col. 1). Therefore, Haas et al teach a method of producing a hydrolyzed product, said method comprising contacting a lecithin material, comprising phospholipids and triglycerides, in an aprotic organic solvent medium comprising sufficient water to promote hydrolysis, with a lipase which selectively hydrolyzes the triglycerides, in the absence of any phospholipase (Claims 29, 30 and 32).

Regarding the percentage of the substrate which was phospholipids, Haas et al teach approximately 53% of the phospholipid-triglyceride mixture was phospholipids (25 mM semi-pure phospholipids and 22 mM soy triglycerides) (See Haas et al, Pg. 520, col. 2). However, the percentage of phospholipids in the initial phospholipid-triglyceride product is a result effective variable that would be routinely optimized by one of ordinary skill in the art. It is clear that the percentage of phospholipids present in the initial substrate was a choice of experimental design, as Haas et al provided roughly equal proportions of phospholipids and triglycerides in the initial substrate; optimization of the proportions of each component would be a routine matter based on the concentration and activity of the enzymes added to the substrate for hydrolysis. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Also note that where the claimed ranges overlap or lie inside ranges disclosed by the prior art a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (Claim 33).

Regarding the percentage acetone insoluble content and the acid value of the resulting hydrolyzed product, Haas et al does not report such measurements; however, one of ordinary skill in the art recognizes that both the acetone insoluble content and the acid value are variables that are directly controlled by optimizable parameters within the hydrolysis process. For example, the acid value is a direct result of the reaction time and the degree of hydrolysis that occurs. Additionally, the acetone insoluble content is representative of the amount of phospholipids present in the initial lecithin material; depending on the purity of the native lecithin, the percentage of phospholipids initially present in the material, and the degree of hydrolysis, the acetone insoluble content can be altered. Therefore, by

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increasing the phospholipid content of the starting lecithin material, by purification, or by purchasing a lecithin material with a desired high acetone insoluble content, one of ordinary skill in the art can increase the acetone insoluble content to above 60% (Claims 35 and 36). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 17 July 2006 have been fully considered.

In their response to the rejection under 35 USC 112, second paragraph, applicants present arguments to each of the three standing grounds of rejection, these arguments are found persuasive:

In response to the rejection of claims 1, 18, and 29 as being incomplete for failing to recite a recovery step, applicants have amended each of the independent claims to recite a recovery step of the lecithin product; thus these rejections are withdrawn.

In response to the rejection of claims 1, 18 and 29 for failing to particularly point out and define the amount of water considered to be "sufficient ...to promote hydrolysis" applicants argue that, in the context of the present application and in view of the teachings of the prior art, one of ordinary skill in the art would easily recognize the amount of water necessary to promote hydrolysis is unique to the system chosen and would then be routinely optimized by one of ordinary skill without undue experimentation. In light of applicants arguments, the examiner concedes that, in view of the teachings of the instant specification and the prior art, that one of ordinary skill in the art would be able to determine by routine experimentation the quantity of water considered to be 'sufficient' to promote hydrolysis. Furthermore, it is noted that the claim does require the amount of water to be sufficient *to promote hydrolysis*, so the end result is not variable, but is a definite outcome by which one could determine the appropriate amount of water necessary. Therefore, this rejection is withdrawn.

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In response to the rejection of claims 11, 25 and 31 in that if the lecithin material is a retentate from a vegetable oil membrane degumming process it would be void of triglycerides, and thus not be suitable for the instant method which requires both triglycerides and phospholipids, applicants argue that a true 'degumming process' does not effectively remove 100% of the triglycerides, but only concentrates the lecithin material by increasing the proportion of phospholipids, without completely removing all triglycerides. Applicants point to their reference to Jurjis (US Pat. No. 6,207,209) for teachings on a degumming process which effectively concentrates the phospholipid component without entirely removing the triglyceride component. In light of applicants explanation of a true 'degumming process', and in view of the reference to Jurjis' method of degumming which does not result in complete removal of triglycerides, the rejection is withdrawn.

In response to the rejections under 35 USC 102(b) and under 35 USC 103(a) based on Haas et al (J American Oil Chem. Soc., 1995), applicants argue that Haas et al was published after the filing date of the instant application, and thus is not prior art; however, applicants appeared to have erred in this statement, Haas et al was published in 1995, whereas the filing date of the instant application is 2004 (nine years later). The rejections over Haas et al stand for the reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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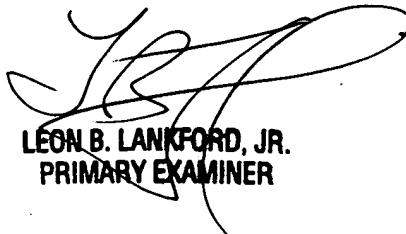
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651


LEON B. LANKFORD, JR.
PRIMARY EXAMINER